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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,368

08/06/2003

Kenneth Stewart

6714-46501

6917

23646 7590 10/02/2009
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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

10/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/634,368	Applicant(s) STEWART, KENNETH	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) 35,37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34,36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-34, 36, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellman (US Patent 4,428,375).

Ellman discloses a device (Figures 1-4) comprising: a hollow cap (15) made of absorbable Dacron™ (Column 2, Lines 30-40) and capable of removal in a subsequent surgical procedure; a separate tubular cinch ring (20 and 22 together) having openings (one opening defined by the enclosed circles of either 20 or 22; a second opening defined by the space between 20 and 22 – same opening direction as those of 19); adjustable, multiple, sutures (16) of the cap (15) that are "threaded" through the openings of the cinch ring. The device may further be non-adjustable and a suture (21)

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ties to the lower edge of the cap and attached to the cinch ring, or may be considered to have a drawstring (21) within the cinch ring to circumferentially tighten the hollow cap. The structure of the device also provides for pleats in between the sutures and ribs of the bag. It is noted that the device is also fully capable of being sized and shaped for separating bone instrumentation from the surrounding body tissues. In the same way that Ellman protects an organ from the surrounding tissues, it could also protect the body from any projecting portion of bone instrumentation.

Claims 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Coombs et al. (US patent 4,564,007) hereafter Coombs. Coombs discloses a combination of a bone implant and a barrier comprising a bone implant (see Fig. 8, 35/36) and a barrier (37) that covers the portion of the implant which projects from the bone. The fit between the cover and the projecting portion of the implant may be considered to have a snug fit. The device is fully capable of creating and providing a medically safe barrier to protect soft tissue, which may also prevent ingrowth.

Additionally, with regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Ellman, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coombs and Ellman, respectively. Coombs and Ellman, respectively, teach the claimed invention except for the cap also being made of a hydrogel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the devices of Ellman and Coombs having a hydrogel material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant arguments submitted 4/14/2009 have been fully considered but are only partially persuasive. Applicant amendments and arguments with respect to the rejections under 112 and 101 have been considered and are persuasive and withdrawn. However with respect to applicant's arguments with respect to the language that the cap is used to separate surrounding soft tissue from the projecting instrumentation, it is noted that this is considered a functional limitation of the structure. Thus, the cover is fully capable of providing and being this barrier.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775